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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,874	02/07/2001	Cavazza Claudio	200427US0CONT	5366

22850 7590 03/06/2002

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/777,874	Cavazza
Examiner	**Art Unit**
Gollamudi S. Kishore, Ph.D	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 2, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11-18 and 20-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11-18 and 20-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Preliminary amendment dated 2-7-01 is acknowledged.

Claims included in the prosecution are 11-18 and 20-31.

Claim Rejections - 35 U.S.C. § 103

1. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

2. **Claims 11-18 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigand cited above by itself or further in view of Moffett (5,536,516).**

Weigand teaches that the anti-obesity compound can be administered along with other anti-obesity compounds (column 3). Weigand however, does not specifically teach that compound to be hydroxy citrate or that hydroxycitrate be in the form of Garcinia extract. The use of an art known anti-obese agent such as hydroxycitrate in combination

with carnitine would have been obvious to one of ordinary skill in the art since Weigand advocates such a use. An artisan would be further motivated to use hydroxycitrate or hydroxycitrate containing Garcinia extract since Moffet teaches that this compound is known to reduce the body weight and therefore prepares a concentrate rich in this compound from Garcinia (note the abstract, col. 1, line 5 et seq.)

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Wiegand is directed to the combination of carnitine and pantothenic acid, but not the combination of acetyl-L-carnitine and hydroxycitric acid and that Moffett is directed to hydroxycitric acid from Garcinia rind and Moffett does not suggest acetyl-carnitine. Applicant is incorrect in stating that Wiegand is directed to carnitine; Wiegand on col. 2, line 42 clearly teaches acetyl-carnitine. The examiner agrees that Wiegand does not teach hydroxycitric acid; however, as pointed above, Wiegand teaches the combination of acetyl-carnitine along with other anti-obesity compounds, but points out that one of ordinary skill in the art would be motivated to combine two components having the same effect with the expectation of obtaining at least an additive effect (see In re Kerhoven 205 USPQ 1069). With regard to synergism argued by applicant, the examiner points out that a careful examination of the data shows just an additive effect. For e.g., the values for hydroxycitrate at 1 g/100 g diet and 2 g/ 100 g diet in the table on page of the declaration are 46.6 + 4.1 and 38.9 + 3.8 respectively, compared to the control values of 62.8+3.5: the value for acetyl carnitine at 2 g/100 g diet 60.4 + 7.1: the combined

value of hydroxycitrate and acetyl-carnitine as noted from this table is 31.6 +3.9. This value is the same as that observed with hydroxycitrate taking into consideration the stand deviation. This value is not even additive. Similar is the case with values reported in tables on pages 4 and 5. Furthermore, the scope of the claims is not commensurate with the amounts recited in the tables.

3. Claims 11-18 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination.

Hastings teaches dry formulations containing calcium salt of hydroxy citric acid, L-carnitine salt, Chromium, antioxidants and other components for weight loss (note the abstract, columns 1-5, examples and claims). Although Hastings does not specifically teach that the composition is in the form of semi-solid, semi-liquids, such is inherent since Hastings teaches the mixing of the composition with a liquid and depending upon the dissolvability of the composition, one would end up with a semi-solid composition. As pointed out above, Hastings teaches the oral administration of a composition containing carnitine and hydroxy citric acid. Hastings' does not however, teach various forms of the composition, such as a tablet or capsule or other claimed forms. It is deemed obvious to an artisan to select a proper form of the composition from Hastings' oral administration of the same composition, to obtain the best possible results. Hastings does not teach alkanoyl-

carnitine. It would however be obvious to an artisan to use various forms of carnitine from Hastings' teachings with the expectation of obtaining at least similar results since the active agent is carnitine.

Weigand teaches compositions containing carnitine or esters of carnitine and pantothenic acid for the treatment of obesity. The composition can be administered orally or parenterally (note the abstract, columns 2-3 and claims).

Burtle teaches compositions containing carnitine or esters of carnitine and pantothenic acid (note the abstract, column 7 and claims).

The use of various forms of carnitine such as esters instead of carnitine itself as taught by Hastings would have been obvious to one of ordinary skill in the art since the references of Burtle and Wiegand show that the esters of carnitine are known to be used for the treatment of obesity; one would expect at least similar results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the lack of teachings of acetyl-carnitine in Hastings and the observed apparent synergistic effect with the combination. These arguments are similar to those put forth for the rejection of claims over Wiegand and Moffett and hence the same response from the examiner as above, is applicable.

4. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657)

individually or in combination, further in view of applicant's statements of prior art.

Hastings, Wiegand and Burtle do not teach the addition of hydroxy citric acid in the form of a natural plant extract containing said acid. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to add the claimed extracts which according to applicant are well known extracts containing the hydroxy citric acid (page 4 of the specification), with the expectation of obtaining at least similar effect as that observed with the hydroxy citric acid itself.

Applicant provides no specific arguments regarding this rejection and therefore, the rejection is maintained.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings cited above by itself, or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination, further in view of Weiner (1989) by itself or in combination with Stracher (5,008,288).

The references of Hastings, Wiegand, Burtle do not teach the administration of the composition in liposomes as vehicles.

The use of liposomes as carriers for the composition containing carnitine would have been obvious to an artisan since Weiner teaches the advantages of liposomes as drug delivery devices (note page 1523 and 1553) and also in view of the art known use of

liposomally encapsulated carnitine derivatives. Applicant has not shown any unexpected results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the apparent observed synergistic effect with the combination. This argument has been addressed above.

6. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand or Burtle; or Wiegand in view of Moffett: or Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination as set forth above, further in view of Cavazza (4,268,524).

Weigand, Burtle, Moffett and Hastings do not explicitly teach that the carnitine derivatives lower cholesterol and triglyceride levels.

Cavazza teaches that acetylcarnitine lowers both cholesterol and triglyceride levels (note the entire patent). It would have been obvious to one of ordinary skill in the art that the compositions taught by Wiegand, Burtle, Moffett and Hastings would lower cholesterol and triglycerides and therefore could be used for hypertriglyceridaemia and hypercholestolaemia.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the apparent observed synergistic effect with the combination. This argument has been addressed above.

7. **Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

February 28, 2002